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Development of selective stability indicating HPLC-DAD method for determination of Milrinone and its degraded products

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Abstract

In this study, a stability indicating Reversed-Phase High Performance Liquid Chromatography (RP-HPLC) method for determination of Milrinone and its degraded products was developed. Methanol and Water (pH 3) was chosen as solvent system in the ratio of 10:90. The flow rate was 1.0ml/min and all absorbance values were carried out at 325nm. EZ Chrome elite software, C18 column and DAD (Diode array detector) was used. The responses were linear in the range of 2-25µg/ml, the regression equation of the calibration graph and correlation coefficient were found to be $y = 20352x - 21632$ and 0.994 respectively. The method was found to be specific which was concluded based on the peak purity (99.4 %) plot where the purity angle is less than purity threshold. The % RSD values for both inter and intraday precision were less than 2%. The LOD and LOQ of Milrinone were determined to be 0.85µg/ml and 2.59 µg/ml respectively. The proposed method was validated for specificity, linearity, intermediate precision, robustness etc. Furthermore, the forced degradation studies of Milrinone were carried under acidic, alkaline, oxidative, thermal and photolytic conditions as per International Conference on Harmonization (ICH) guidelines of stability testing. In conclusion, the method was observed to have the necessary specificity, precision and accuracy to be suitable for quantity monitoring degradation process of Milrinone during forced degradation studies.

Key words: DAD, linearity, Milrinone, Specificity, Stability indicating

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